

***Understanding the Formaldehyde Science and  
Putting the Puzzle Pieces Together –  
Integrating New Science into Risk Evaluation  
Processes***

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Ramboll Environ

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# Hazard Characterization

## **Conclusions regarding formaldehyde carcinogenicity**

- *Regulatory Conclusions* – inconsistencies between EPA, ECHA, WHO, IARC, and NTP regarding the potential carcinogenicity of formaldehyde
- *Diseases of Concern* - nasopharygeal (NPC) and all lymphohematopoietic (LHP) cancers
  - Some focus by selected agencies on the specific diseases - Acute Myeloid Leukemia (AML)
- *NPC specific questions* - the potential for a threshold and rarity of the tumor
- *LHP specific questions* - the biological plausibility of formaldehyde exposure causing all LHP cancers versus specific subtypes

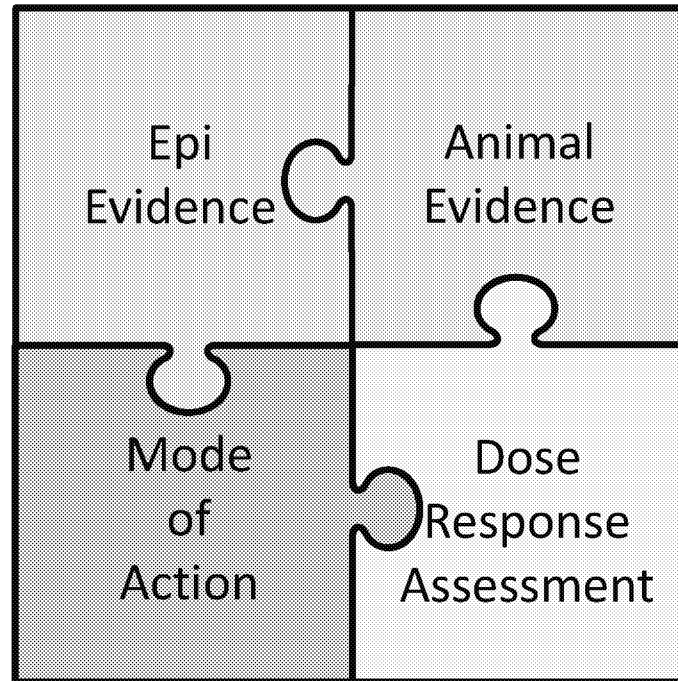
# Hazard Characterization

## *Approaches to discuss:*

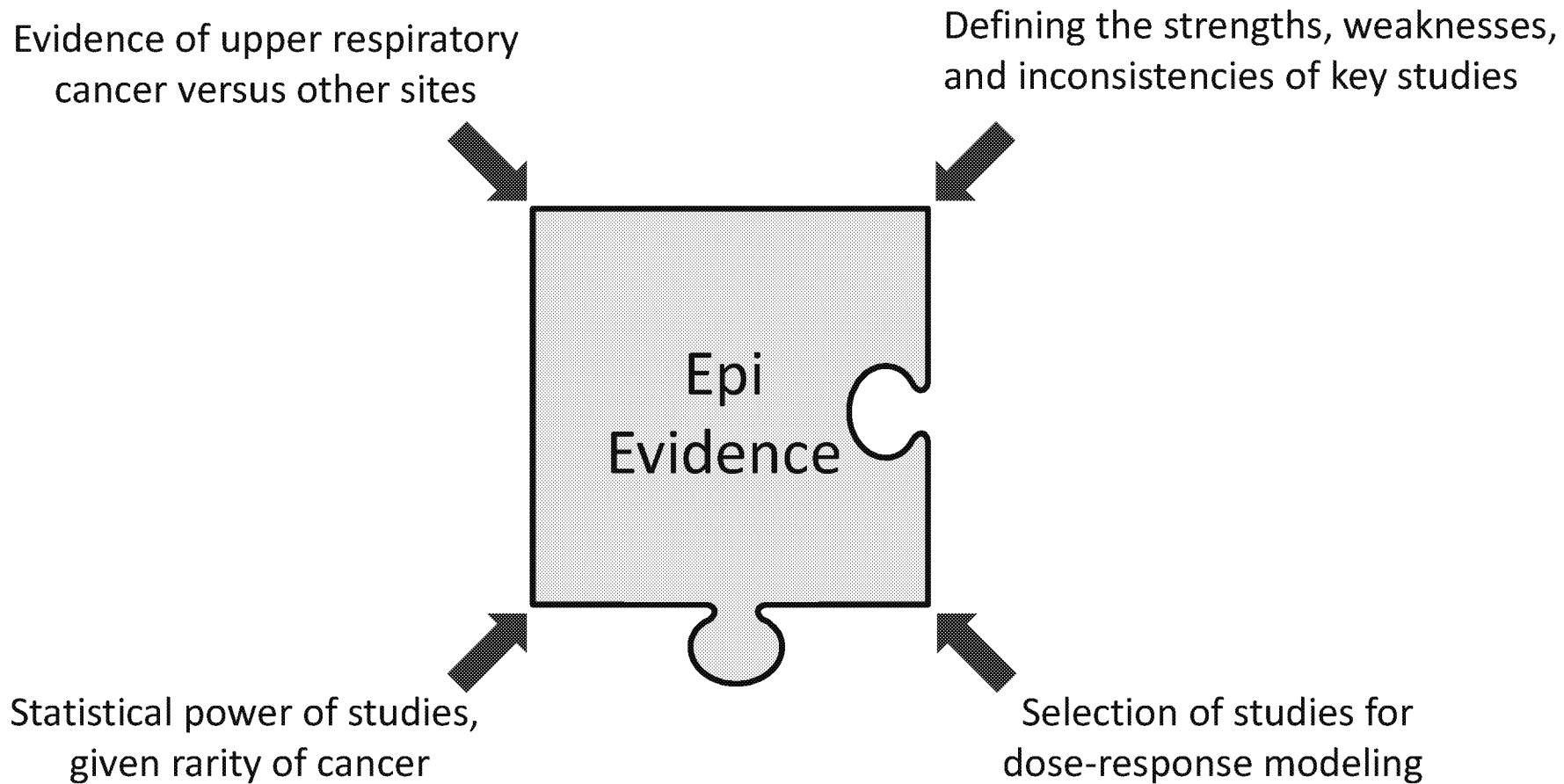
**Conclusions  
regarding  
formaldehyde  
carcinogenicity**

- *Systematic Review* – protocol development, evidence identification, evidence evaluation, analytic summary of the evidence
- *Weight of Evidence* – a summary, considering both the quality and quantity of data to support conclusions regarding human carcinogenic potential
- *Evidence Integration* – qualitative or quantitative approaches to integrate multiple streams of evidence to reach determinations of whether or not the evidence is adequate to draw conclusions related to potential hazard and causality
- *Mode of action (MOA) frameworks* – evaluation of the available mechanistic or mode of action data in a systematic way to determine which proposed MOAs are supported by the available evidence and support causality and relevance to humans

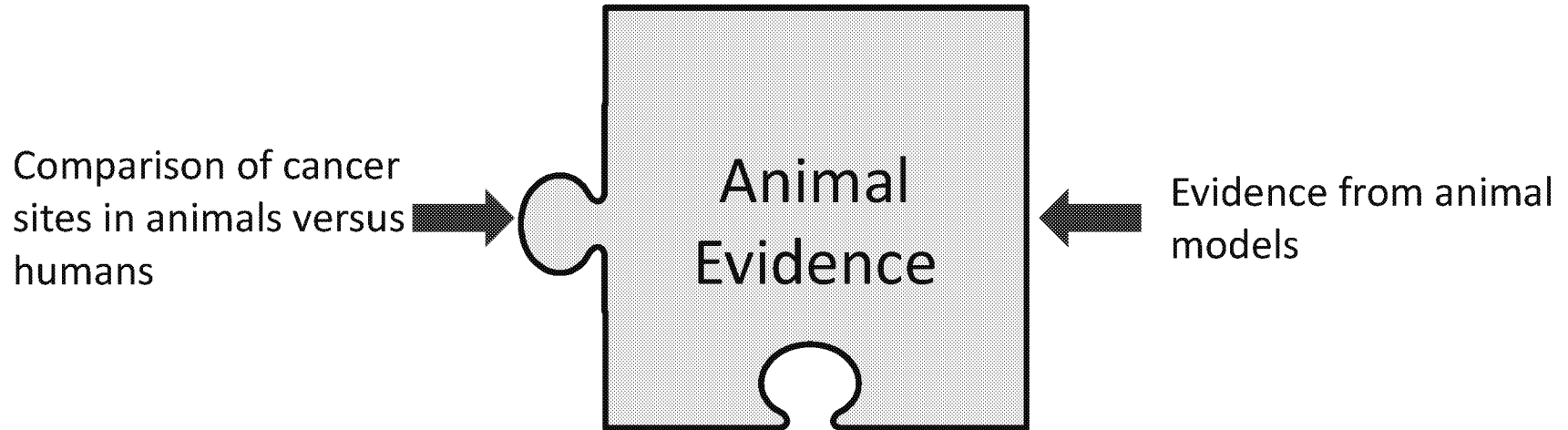
# Integration of Evidence and Determination of Causality



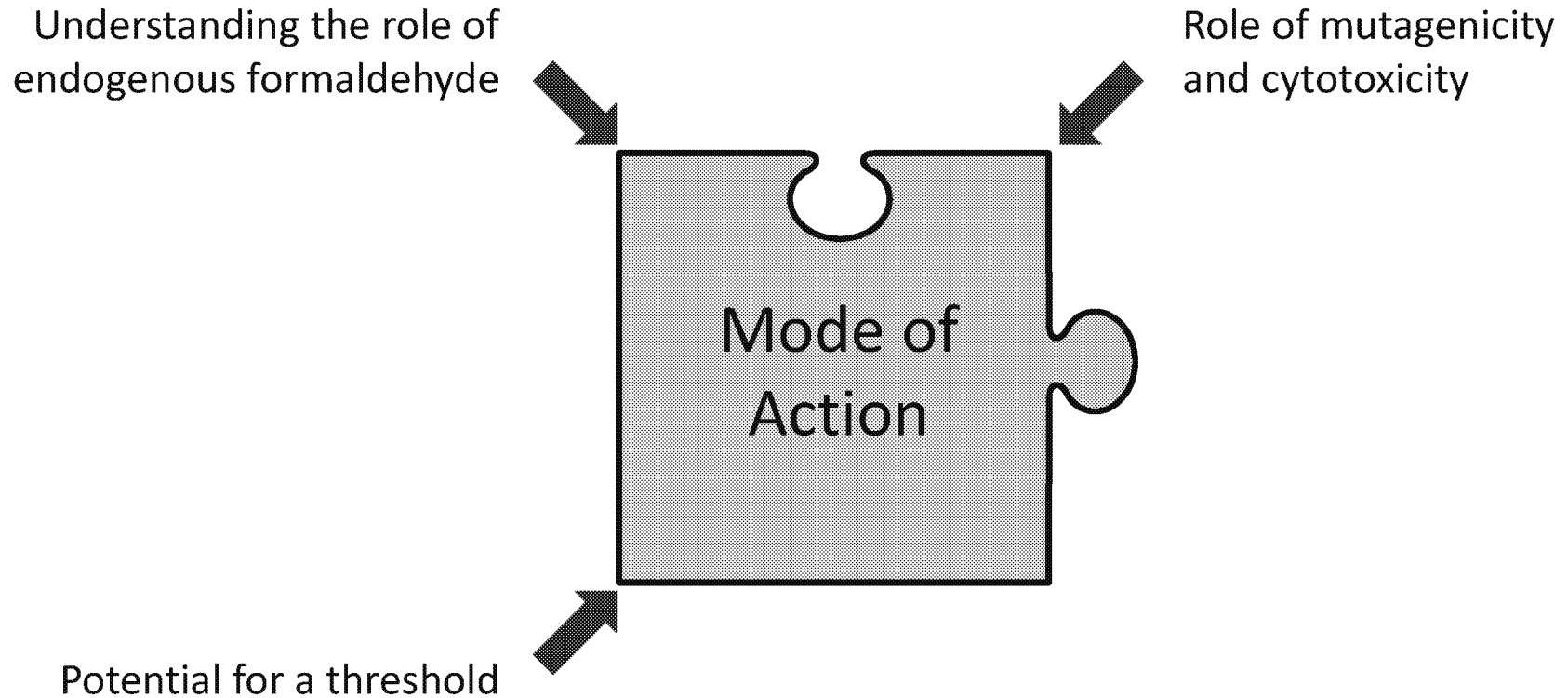
# NPC – Epidemiological



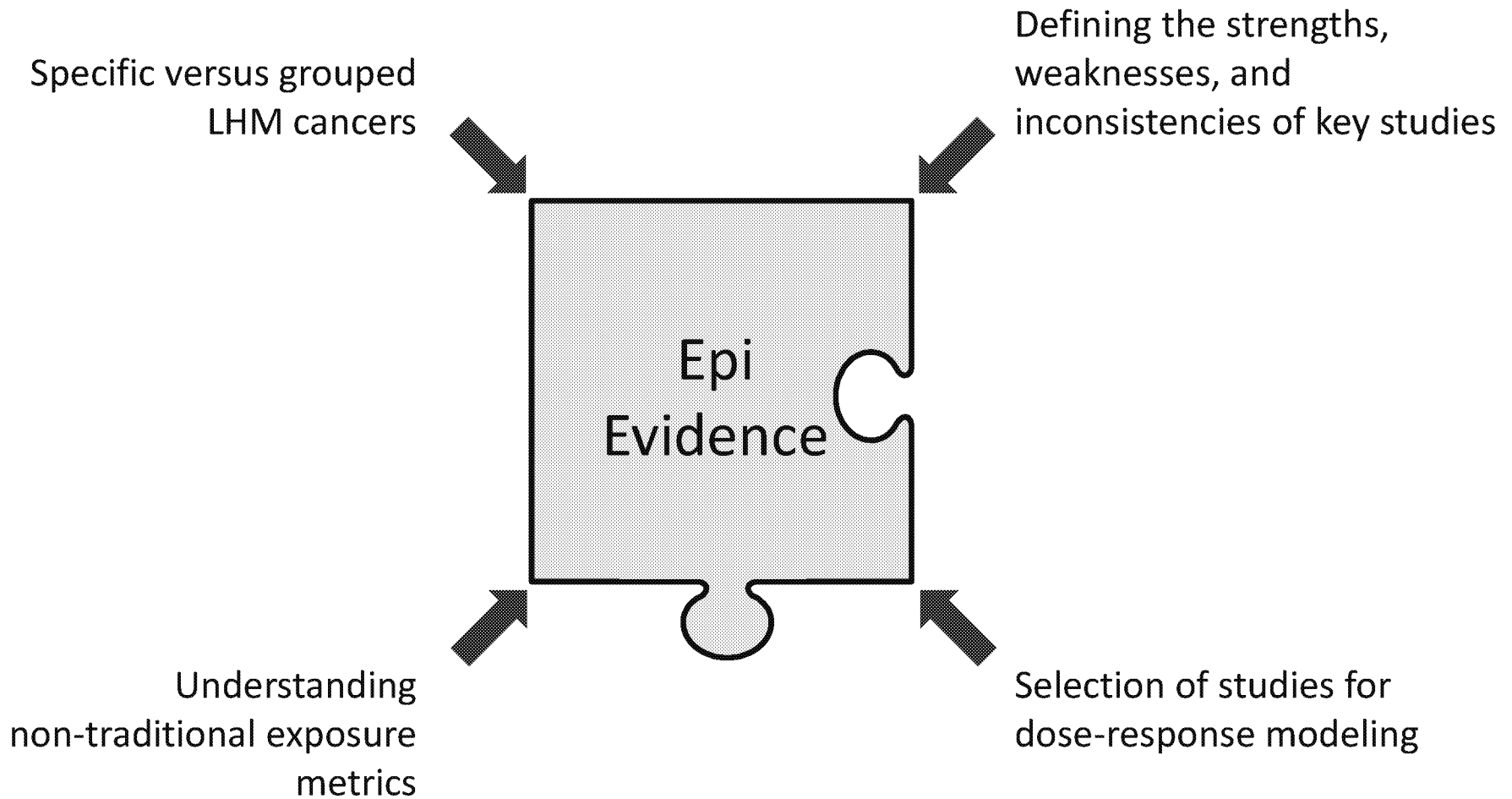
# NPC - Animal



# NPC – Mode of Action

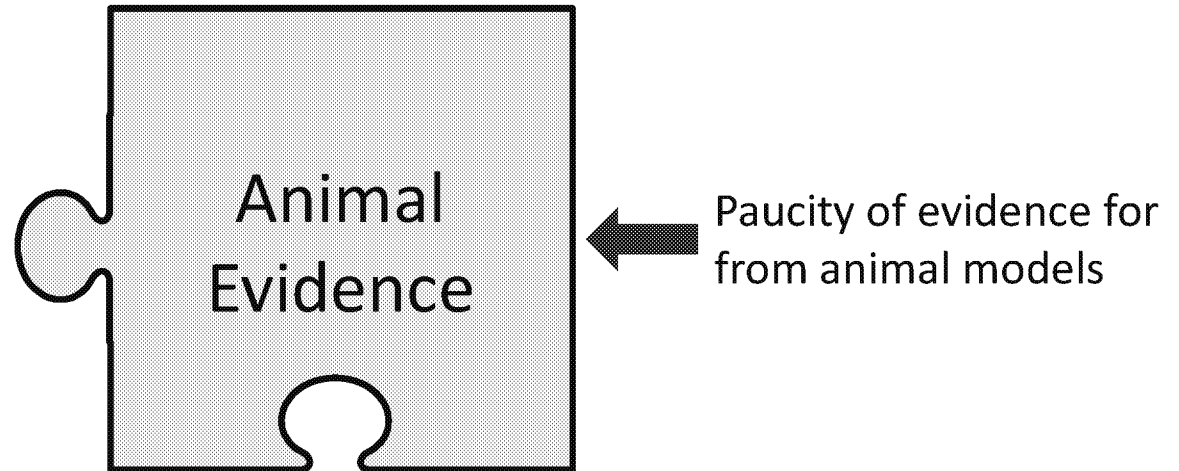


# LHP – Epidemiological

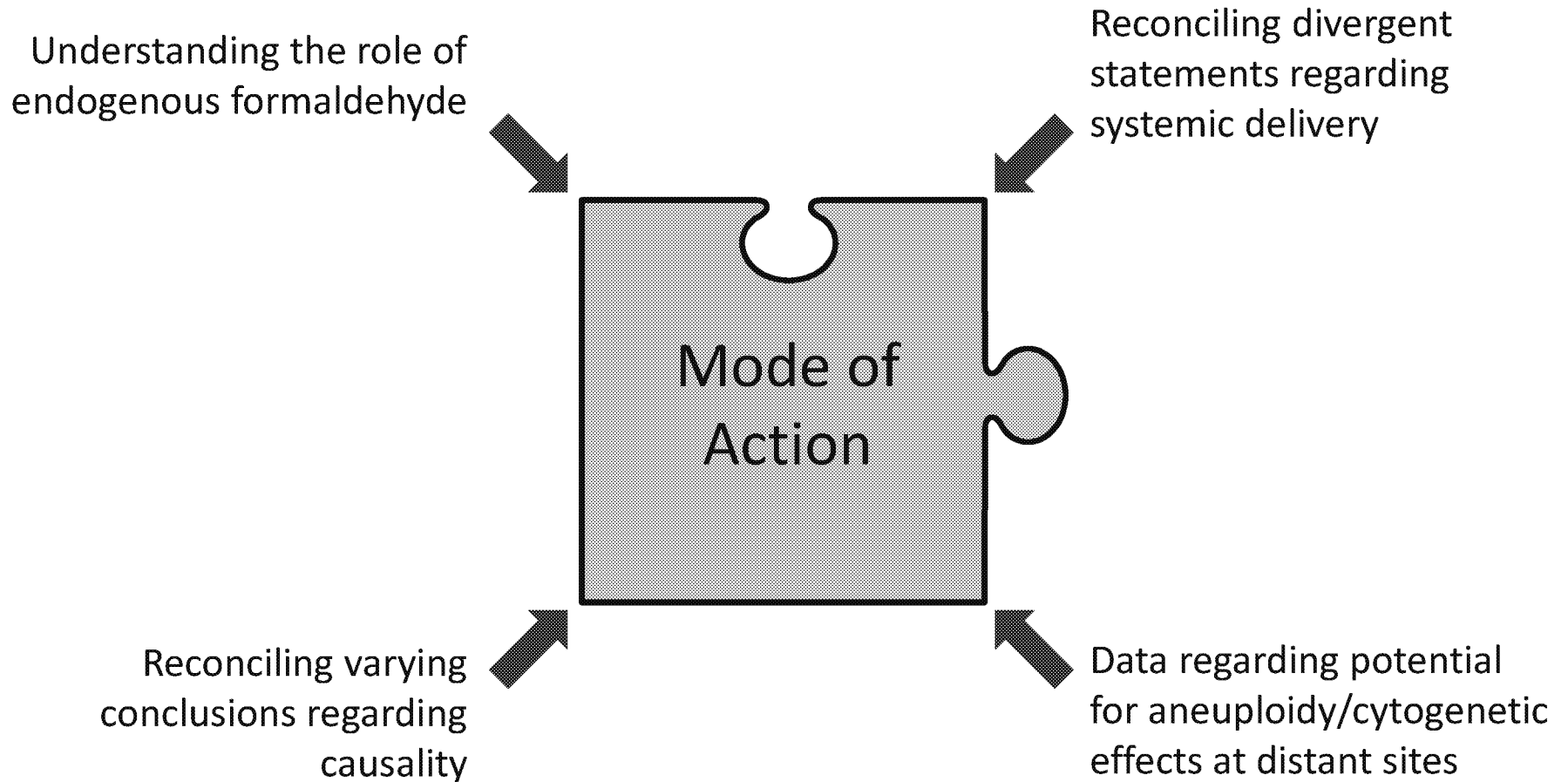




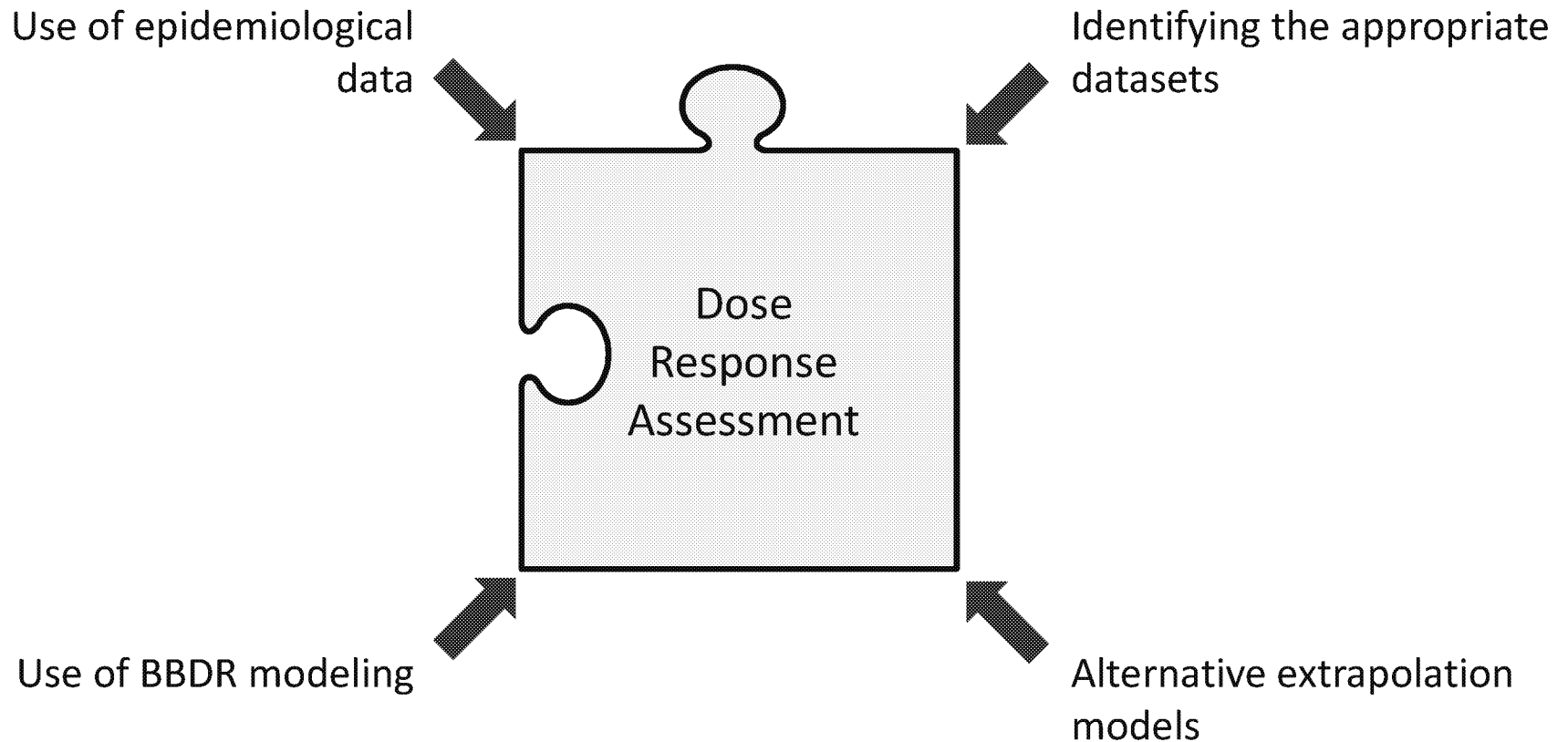
# LHP - Animal



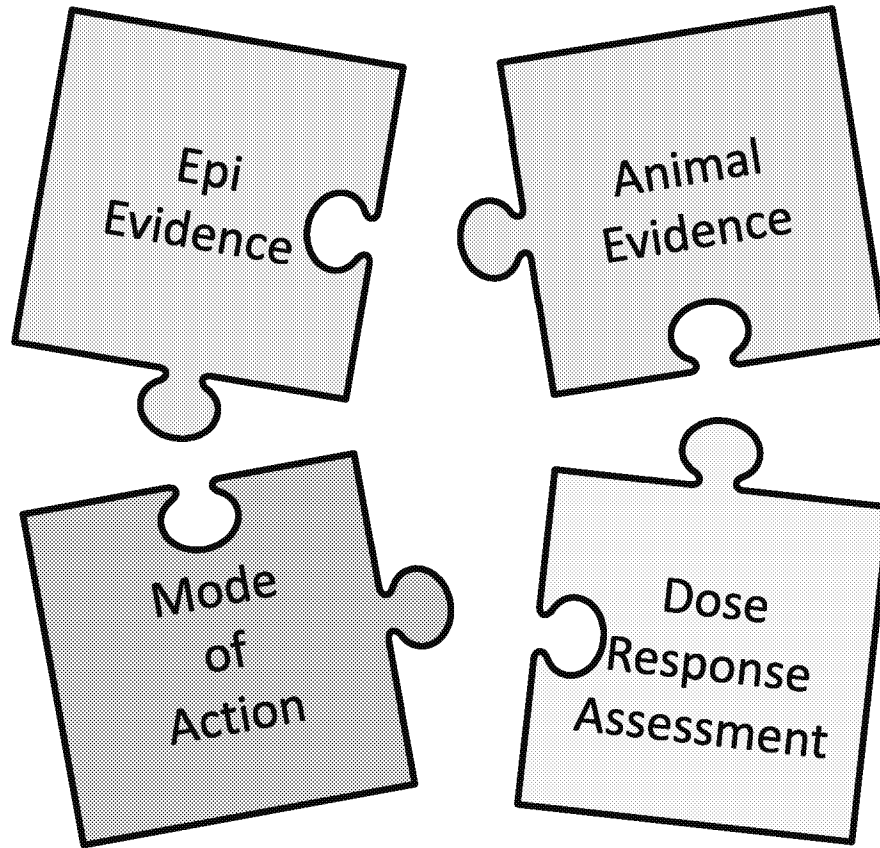
# LHP – Mode of Action



# Quantitative Analyses for Cancer



# Putting the pieces together



*How do we set up the framework for conducting a risk assessment for formaldehyde integrating the best available science and methods?*